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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,800	12/20/2001	Julio C. Spinelli	279.372US1	9417
21186	7590	09/10/2004		
			EXAMINER	
			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,800	SPINELLI ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 June 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 December 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-15, 17-27, 29, 30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Lu (Pat. No. 6,654,639).

Regarding claim 1 and claims with similar limitations, Lu discloses a cardiac rhythm management system including a plurality of electrodes, sized and shaped to be associated with a heart (see Fig. 1); a cardiac signal detector circuit, coupled to the electrodes (note elements 82 and 84 of Fig. 2); an energy output circuit, coupled to at least one of the electrodes (note elements 70, 72 and 116); and a controller coupled to the cardiac signal detector and the energy output circuit (60), the controller including an arrhythmia detector module (the element labeled “arrhythmia detection”); an arrhythmia classifier module, to classify the detected arrhythmia according at least to a sequence in which a heart contraction depolarization is received at the electrodes (note for example col. 2, lines 14-22); a therapy map, providing an anti-arrhythmia therapy corresponding to the arrhythmia classification (see col. 14, lines 51-58); and a control signal to be issued to the energy output circuit to deliver a selected anti-arrhythmia therapy corresponding to an arrhythmia classification (see col. 5, lines 53-56).

Regarding claim 9 and claims with similar limitations, note col. 11, lines 4-28.

Regarding claim 11 and claims with similar limitations, Lu discloses storing template values that successfully terminated an arrhythmia from a particular chamber and selects the stored settings based on which chamber the tachycardia originates from. By selecting previously successful settings for the chamber of interest, Lu is

inherently selecting therapy based on a success estimate (i.e., if a particular setting for a chamber was successful before, the chances of it being successful again are estimated to be greater than trying settings that may have failed to revert the arrhythmia).

Regarding claim 14 and claims with similar limitations, the device of Lu first attempts ATP for a predetermined number of times, then if attempts are proven to be unsuccessful, escalates to a higher-confidence anti-arrhythmia therapy such as cardioversion or defibrillation (note col. 12, lines 42-66).

Regarding claim 15 and claims with similar limitations, note col. 11, lines 45-61.

Concerning claim 17 and the recited interelectrode delay, the examiner equates such a delay to the interchamber delay periods of Lu which may be adjusted downward as discussed in depth throughout the reference. Related comments apply to claims with similar limitations.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu in view of Adams (Pat. No. 5,425,749).

Lu does not explicitly appear to discuss delivering a defibrillation shock if variability in the classification over a plurality of heart contractions exceeds a predetermined value. Adams, however, teaches that it is important to deliver cardioverting or defibrillating energy as soon as possible after detection of fibrillation in order to increase the patient's chances of survival (col. 1, lines 8-20). By definition, fibrillation is an uncoordinated activation of cardiac cells resulting in locally unstable heart rates. Adams therefore suggests that a measure of rate instability (i.e., rate

variability) may be employed in order to discriminate between fibrillation and other more stable non-fibrillation events (col. 1, lines 39-45). The determination of rate stability/variability is an old and well-known method for detecting fibrillation. Any artisan of ordinary skill in the cardiac therapy art desiring to enhance patient safety by allowing for quick application of defibrillating energy, would have seen the obviousness of providing the device of Lu with the capability to determine rate variability given the teachings of Adams and the general knowledge available in the cardiac treatment arts.

Response to Arguments

5. Applicant's arguments filed June 14, 2004 have been fully considered but they are not persuasive.

The applicants argue that as presently amended, there is no disclosure, teaching, or suggestion in the cited portions of the Lu reference for classifying the detected arrhythmia according to at least a sequence in which a heart contraction depolarization is received at the electrodes during the arrhythmia. Applicants go on to recite a passage from Lu that is asserted to teach away from such a limitation.

The examiner responds that the Lu reference must be considered for all it contains and not just the cited portions. Lu states in col. 11, lines 15-23 that the origin of the arrhythmia can be determined in the presence of the arrhythmia by determining any differences in cardiac interval durations and/or changes in the activation sequence.

Identical comments apply to the arguments presented pertaining to the rejection of claims under Lu in view of Adams.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

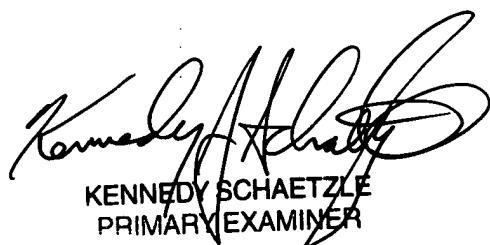
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
September 8, 2004



KENNEDY SCHAETZLE
PRIMARY EXAMINER